

REMARKS

Claims 1–11 are pending in the application. No new matter or claim amendments are entered with this response.

Claims 1–11 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Applicants respectfully request reconsideration and withdrawal of the rejection because the Examiner has not identified any evidence supporting the assertion that those of ordinary skill in the art would not be able to practice the claimed methods.

When rejecting a claim under the enablement requirement of 35 U.S.C. § 112, first paragraph, the Patent Office bears the “initial burden of setting forth a reasonable explanation as to why [it] believes that the scope of protection provided by [the] claim is not adequately enabled by the description of the invention provided in the specification.” *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). To object to a specification on the grounds that the disclosure is not enabling with respect to the scope of a claim sought to be patented, the Examiner must provide evidence or technical reasoning substantiating those doubts. *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971); M.P.E.P. § 2164.04. Without a reason to doubt the truth of the statements made in the patent application regarding practice of the claimed subject matter, the application must be considered enabling. *In re Wright*, 27 U.S.P.Q.2d at 1513; *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971).

The Examiner has not identified objective evidence that persons of ordinary skill in the art would have any such “reason to doubt” Applicants’ enablement of the claimed methods. Although the Examiner questions whether the cells used in Applicants’ reported assays express the orexin-2 receptor, no evidence is cited indicating that such expression does not occur. For example, the abstract upon which the Examiner relies (taken from Fults *et al.*, *J. Neuropathol. Exp. Neurol.* 1992 May;51(3):272-80) states that PFSK-1 cells do not express antigens typically found in terminally differentiated neurons, but is entirely silent as to whether PFSK-1 cells express orexin-2 receptor. In fact, Applicants specifically found that the PFSK-1 cell line expressed the orexin-2 receptor (Specification, page 9, lines 3-7).

The Examiner contends that the PFSK-1 cell line Applicants used might have actually expressed hypocretin receptors, rather than orexin-2 receptors. The stated basis for this contention is that both orexin and hypocretin receptors have been found to have overlapping

ligand affinities and specificities in other cell lines. The contention, however, is at least facially inconsistent with the Examiner's assertion that PFSK-1 cells do not express the antigens typically found in terminally differentiated neurons. Applicants therefore request that the Examiner clarify how in particular she regards the nature of antigen expression in PFSK-1 cells to be analogous to that observed in other types of cells.

The Examiner also questions whether orexin-2 receptors were tested by Applicants because the test protocol used involved Ca^{2+} flux, which has the capacity to detect other types of receptor activity. However, Applicants reported test protocols, employed necessary controls, and provided adequate guidance to allow one skilled in the art to practice the claimed assay (Specification, page 9, line 24, through page 11). Thus, the possibility that techniques involving Ca^{2+} flux can, under certain conditions, provide generic results is of limited relevance, and certainly does not provide any reason to doubt Applicants' considerable teachings regarding practice of the claimed inventions. The Examiner notes that the claims identify the human orexin-2 receptor by name only, rather than by SEQ ID NO, but this fact also fails to indicate any lack of enablement. The Examiner, for example, cites no legal authority indicating that moieties such as the human orexin-2 receptor cannot be claimed by name rather than by SEQ ID NO. Moreover, there is no genuine dispute that those skilled in the art, having read Applicants' disclosure, would be able to practice the claimed methods. . The specification, for example, describes an exemplary cell line that expresses human orexin-2 receptor receptor in PFSK-1 cells (Specification, page 7, lines 21 - 22). As there is no evidence of record so much as suggesting that this teaching would have been inadequate for those skilled in the art to practice the claimed methods, the rejection under Section 112, first paragraph, is improper and should be withdrawn. *In re Wright*, 27 U.S.P.Q.2d at 1513 (specification must be considered enabling absent a reason to doubt the truth of the statements made regarding practice of the claimed subject matter).

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PATENT

CONCLUSION

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, an early and favorable Action is respectfully requested. Should any issues remain unresolved by the present remarks, the Examiner is invited to contact the undersigned at 215.568.3100.

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